In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS No. 19-1535V UNPUBLISHED

JANET NIEMI,

Petitioner,

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SECRETARY OF HEALTH AND HUMAN SERVICES,

Respondent.

Chief Special Master Corcoran

Filed: August 10, 2021

Special Processing Unit (SPU); Findings of Fact; Onset; Influenza (Flu) Vaccine; Shoulder Injury Related to Vaccine Administration (SIRVA)

David John Carney, Green & Schafle LLC, Philadelphia, PA, for Petitioner.

Mollie Danielle Gorney, U.S. Department of Justice, Washington, DC, for Respondent.

FINDINGS OF FACT¹

On October 2, 2019, Janet Niemi filed a petition for compensation under the National Vaccine Injury Compensation Program, 42 U.S.C. §300aa-10, *et seq.*² (the "Vaccine Act"). Petitioner alleges that she suffered a left shoulder injury related to vaccine administration (SIRVA) after receiving an influenza ("flu") vaccination on January 16, 2019. ECF 32 at 1-2. The case was assigned to the Special Processing Unit of the Office of Special Masters.

¹ Because this unpublished Fact Ruling contains a reasoned explanation for the action in this case, I am required to post it on the United States Court of Federal Claims' website in accordance with the E-Government Act of 2002. 44 U.S.C. § 3501 note (2012) (Federal Management and Promotion of Electronic Government Services). **This means the Fact Ruling will be available to anyone with access to the internet.** In accordance with Vaccine Rule 18(b), petitioner has 14 days to identify and move to redact medical or other information, the disclosure of which would constitute an unwarranted invasion of privacy. If, upon review, I agree that the identified material fits within this definition, I will redact such material from public access.

² National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3755. Hereinafter, for ease of citation, all section references to the Vaccine Act will be to the pertinent subparagraph of 42 U.S.C. § 300aa (2012).

For the reasons discussed below, I find that the onset of Petitioner's SIRVA more likely than not occurred within 48 hours of vaccination.

I. Relevant Procedural History

After an initial status conference in February 2020, Petitioner was ordered to file outstanding medical records. ECF 12. Over the next several months, Petitioner submitted additional records, and she filed an amended statement of completion in June 2020. ECF 17. On January 29, 2021, Respondent filed a status report indicating that he was interested in pursuing settlement discussions. ECF 24. One month later, Petitioner reported that the parties had reached an impasse in their negotiations. ECF 27. Respondent was subsequently ordered to file a Rule 4(c) report.

In his report, Respondent asserts that there is not a preponderance of evidence demonstrating the requisite facts necessary to establish a Table SIRVA injury. ECF 28. Specifically, Respondent argues that "the medical records do not establish that [P]etitioner suffered the first symptoms or manifestation of onset of a shoulder injury within 48 hours of the January 16, 2019 flu vaccination." *Id.* at 7. Petitioner then requested that she be allowed the opportunity to file a motion for a ruling on the record. ECF 29. On May 25, 2021, Petitioner filed her Motion for Ruling on the Record and Brief in Support of Damages.³ ECF 31. Respondent filed his responsive brief one month later. ECF 34. Therefore, this matter is ripe for adjudication.

II. Issue

At issue is whether Petitioner's first symptom or manifestation of onset after vaccine administration (specifically pain) occurred within 48 hours as set forth in the Vaccine Injury Table and Qualifications and Aids to Interpretation ("QAI") for a Table SIRVA. 42 C.F.R. § 100.3(c)(10)(ii).

III. Authority

Pursuant to Vaccine Act Section 13(a)(1)(A), a petitioner must prove, by a preponderance of the evidence, the matters required in the petition by Vaccine Act Section 11(c)(1). A special master must consider, but is not bound by, any diagnosis,

³ While Petitioner briefed damages in her Motion for Ruling on the Record, she had been advised in the Scheduling Order dated May 11, 2021, to limit her argument to the issue of entitlement. ECF 29. Pursuant to this order, Respondent addressed only the issue of entitlement in his brief. ECF 34. Accordingly, I find Petitioner's briefing of damages premature (although if any further briefing of damages is called for, Petitioner will be given the opportunity to update or supplement any facts or argument made on this subject to date).

conclusion, judgment, test result, report, or summary concerning the nature, causation, and aggravation of petitioner's injury or illness that is contained in a medical record. Section 13(b)(1). "Medical records, in general, warrant consideration as trustworthy evidence. The records contain information supplied to or by health professionals to facilitate diagnosis and treatment of medical conditions. With proper treatment hanging in the balance, accuracy has an extra premium. These records are also generally contemporaneous to the medical events." *Cucuras v. Sec'y of Health & Human Servs.*, 993 F.2d 1525, 1528 (Fed. Cir. 1993).

Accordingly, where medical records are clear, consistent, and complete, they should be afforded substantial weight. *Lowrie v. Sec'y of Health & Human Servs.*, No. 03-1585V, 2005 WL 6117475, at *20 (Fed. Cl. Spec. Mstr. Dec. 12, 2005). However, this rule does not always apply. In *Lowrie*, the special master wrote that "written records which are, themselves, inconsistent, should be accorded less deference than those which are internally consistent." *Lowrie*, at *19.

The United States Court of Federal Claims has recognized that "medical records may be incomplete or inaccurate." *Camery v. Sec'y of Health & Human Servs.*, 42 Fed. Cl. 381, 391 (1998). The Court later outlined four possible explanations for inconsistencies between contemporaneously created medical records and later testimony: (1) a person's failure to recount to the medical professional everything that happened during the relevant time period; (2) the medical professional's failure to document everything reported to her or him; (3) a person's faulty recollection of the events when presenting testimony; or (4) a person's purposeful recounting of symptoms that did not exist. *La Londe v. Sec'y of Health & Human Servs.*, 110 Fed. Cl. 184, 203-04 (2013), *aff'd*, 746 F.3d 1335 (Fed. Cir. 2014).

The Court has also said that medical records may be outweighed by testimony that is given later in time that is "consistent, clear, cogent, and compelling." *Camery*, 42 Fed. Cl. at 391 (citing *Blutstein v. Sec'y of Health & Human Servs.*, No. 90-2808, 1998 WL 408611, at *5 (Fed. Cl. Spec. Mstr. June 30, 1998). The credibility of the individual offering such testimony must also be determined. *Andreu v. Sec'y of Health & Human Servs.*, 569 F.3d 1367, 1379 (Fed. Cir. 2009); *Bradley v. Sec'y of Health & Human Servs.*, 991 F.2d 1570, 1575 (Fed. Cir. 1993).

A special master may find that the first symptom or manifestation of onset of an injury occurred "within the time period described in the Vaccine Injury Table even though the occurrence of such symptom or manifestation was not recorded or was incorrectly recorded as having occurred outside such period." Section 13(b)(2). "Such a finding may be made only upon demonstration by a preponderance of the evidence that the onset [of

the injury] . . . did in fact occur within the time period described in the Vaccine Injury Table." *Id*.

The special master is obligated to fully consider and compare the medical records, testimony, and all other "relevant and reliable evidence contained in the record." *La Londe*, 110 Fed. Cl. at 204 (citing Section 12(d)(3); Vaccine Rule 8); *see also Burns v. Sec'y of Health & Human Servs.*, 3 F.3d 415, 417 (Fed. Cir. 1993) (holding that it is within the special master's discretion to determine whether to afford greater weight to medical records or to other evidence, such as oral testimony surrounding the events in question that was given at a later date, provided that such determination is rational).

IV. Finding of Fact

I make these findings after a complete review of the record, including all medical records, affidavits, testimony, expert reports, respondent's Rule 4 report, and additional evidence filed. Specifically, I base the findings on the following evidence:

- On January 16, 2019, Petitioner received an intramuscular flu vaccine in her left deltoid. Ex 1 at 2-3.
- On February 14, 2019, Petitioner visited the emergency room (ER) for a head injury after falling off a chair at work. Ex 10 at 59. While at the ER, Petitioner did not report pain in any extremities and physical examination (PE) revealed full range of motion. *Id.* at 61.
- On February 19, 2019, Petitioner followed up telephonically with a nurse at her primary care provider's (PCP) office for her head injury. Ex 3 at 49. During the call, she denied difficulty moving her arms. *Id*.
- On March 5, 2019, Petitioner visited her PCP to discuss her fall in February 2019. Ex 3 at 51. She now also reported left arm pain and decreased range of motion "after" receiving her flu shot. Id. She showed decreased range of motion in the left shoulder, and the PCP questioned if an intra-articular injection of the flu vaccine caused Petitioner's injury. Id. at 53. Petitioner was referred to an orthopedist. Id.
- On March 20, 2019, Petitioner presented to Dr. Daniel Bauk, an orthopedist, with a complaint of "got her flu shot on January 17 [sic], 2019, and the next day began having pain in her shoulder." Ex 5 at 8. Dr. Bauk's exam revealed diffuse tenderness to palpation and pain with range of motion, and he diagnosed Petitioner with adhesive capsulitis. *Id.* at 9.
- On April 11, 2019, Petitioner underwent an initial evaluation for physical therapy, at which time she reported left shoulder pain with onset of

January 17, 2019 after receiving a flu vaccine that was injected "too high" on her shoulder. Ex 9 at 11.

- On September 13, 2019, Petitioner had a consultation with Dr. Peter Johnston, another orthopedist. Ex 8 at 4. She complained of "flu shot back in January and since has been struggling with significant left shoulder pain." Id.
- In her affidavit, Petitioner states that "within two days of receiving the injection, [she] began to experience pain in [her] arm at the injection site that spread to [her] shoulder over the ensuing days." Ex 2 at 2.

Respondent argues that the seven-week gap between Petitioner's flu vaccine and first recorded report of left arm pain fails to support onset within 48 hours. ECF 34 at 6-8. He specifically focuses on the fact that Petitioner sought medical care twice between the time she received the subject vaccination and the first time she reported shoulder pain to a medical provider. *Id.* at 7. However, it was not unreasonable for Ms. Niemi not to have reported shoulder pain at her ER visit, as she was likely focused on treating her head injury, a more concerning medical event.⁴ Additionally, while exam of Petitioner's upper extremities at the ER was noted to be normal, such ER-provided examinations are often cursory, especially when the visit is focused on an emergent injury to another part of the body. Further, while Respondent in his brief characterizes Petitioner's February 19, 2019 contact with her PCP's office as an "intervening medical visit," the record reflects that this was in fact only a phone call with a nurse to specifically discuss her head injury. Ex 3 at 49.

In focusing on the admitted gap in treatment, Respondent seems to be arguing that the only way Petitioner can show she experienced symptoms within 48 hours of vaccination is with contemporaneous records created *within* that two-day timeframe. But the Vaccine Act clearly does *not* require that symptoms be recorded within a specific timeframe to be preponderantly established. Rather, it requires only that onset *occurs* in the relevant timeframe. 42 U.S.C. § 300aa-13. Of course, the reliability of onset evidence may hinge on when and how onset is recorded, and evidence of post-vaccination pain from a record created no more than two days post-vaccination would constitute particularly strong evidence of onset. But a petitioner can still prevail even if the evidence establishing onset comes from a later period. Ultimately, resolving how to weigh the evidence pro and con on such matters falls within the purview of the special masters. *Id*.

Given the above, I find that the two records at issue (specifically Petitioner's report to her orthopedist on March 20, 2019, and her physical therapist on April 11, 2019) are consistent with Petitioner's affidavit testimony that her left shoulder pain began with 48

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⁴ Indeed, the medical records from her ER visit reflect that a CT scan of the brain showed a left posterolateral occipital contusion and a subgaleal hematoma. Ex 10 at 61-63.

hours of vaccination. In addition, I do not find that the gap between vaccination date and Petitioner's first report of shoulder pain greatly weakens the conclusion that her claimed onset "more likely than not" occurred within the timeframe for a Table SIRVA injury. While some cases might be stronger and some weaker, the evidence in this case is enough to preponderantly establish that the onset of Petitioner's left shoulder injury occurred within 48 hours of her January 16, 2019 flu vaccination.

V. Scheduling Order

Given my findings of fact regarding the onset of Ms. Niemi's pain, Respondent should evaluate and provide his current position regarding the merits of Petitioner's case.

Accordingly, Respondent shall file, by no later than <u>Monday, September 13, 2021</u>, an amended Rule 4 report reflecting Respondent's position in light of the above fact finding.

IT IS SO ORDERED.

s/Brian H. Corcoran
Brian H. Corcoran
Chief Special Master